CORPORATE NEWS

EARNINGS

PAION AG REPORTS FINANCIAL RESULTS FOR THE FIRST HALF-YEAR 2019

- NDA for remimazolam filed in the U.S. in April 2019 accepted for review by the FDA in June 2019
- Positive pre-submission meeting with EMA for the indication procedural sedation in the EU
- Financing agreement for EUR 20 million with the European Investment Bank
- Cash and cash equivalents of EUR 19.2 million as of 30 June 2019
- Conference call today at 2:00 p.m. CEST (1:00 p.m. BST/8:00 a.m. EDT)

Aachen (Germany), 07 August 2019 – The specialty pharmaceutical company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange, Prime Standard: PA8) today reports its consolidated financial results according to International Financial Reporting Standards (IFRS) for the first half-year 2019.

Dr. Wolfgang Söhngen, CEO of PAION AG, commented: "*A lot of positive news shaped the first half year 2019. With the filing for market approval for remimazolam in the U.S., our licensee Cosmo has taken an important step towards market entry. In this context, PAION received a milestone payment of EUR 7.5 million. The positive pre-submission meeting in Europe provides the opportunity to file for market approval for remimazolam in the indication procedural sedation with the European Medicines Agency by the end of this year. In this indication, we may be able to launch remimazolam on the European market earlier than expected. In addition, we signed a financing agreement with the European Investment Bank – a significant demonstration of confidence and strong support for our strategy.*"

Update and outlook on remimazolam development

U.S.

The New Drug Application (NDA) in procedural sedation was prepared together with licensee Cosmo Pharmaceuticals (Cosmo) and submitted to the FDA by Cosmo in the beginning of April 2019. The FDA informed Cosmo on 10 June 2019 that the filing has been accepted. The PDUFA date (Prescription Drug User Fee Act) was set for 05 April 2020. The PDUFA date is the target date by which the FDA review is supposed to be completed. However, the FDA has no obligation to actually complete the review by this date.

With a regular course of the approval process, the U.S. market approval and subsequent launch of remimazolam can be expected in 2020.

EU

In Europe, PAION is seeking approval for remimazolam in the indications general anesthesia and now also in procedural sedation. PAION plans to submit a Marketing Authorization Application (MAA) in procedural sedation later this year, following a discussion with the European Medicines Agency (EMA) in the course of a pre-submission meeting held in February 2019 that the existing data package from the U.S. Phase III clinical development program will be sufficient for submitting the MAA for remimazolam in procedural sedation in the EU. The submission is subject to EMA approval of the Pediatric Investigation Plan (PIP). Consequently, PAION expects an earlier market entry in Europe altogether. Following approval in procedural sedation, an extension of the dossier, a so-called type-II variation, would allow for an abbreviated application for general anesthesia that is processed significantly faster. The indication can be extended once market approval in procedural sedation has been granted and the data from the ongoing EU Phase III clinical trial in general anesthesia are available. The randomized, single-blind, propofol-controlled, confirmatory Phase III trial with remimazolam for the induction and maintenance of general anesthesia is expected to enroll approx. 500 ASA III/IV patients (American Society of Anesthesiologists classification III to IV) in Europe undergoing non-emergency surgery.

Currently, more than 200 patients have been treated. The opening of additional sites has been initiated in order to accelerate the recruitment process. Completion of patient recruitment is expected in the first quarter of 2020. Due to the new approval strategy for Europe, this adjustment will probably have no time implication on the planned start of commercialization in general anesthesia. The complete data from the EU phase III study, which are required for the regulatory process of an indication extension by general anesthesia, are expected to be available at the time of approval of the MAA in procedural sedation allowing for the timely application for an extension of the remimazolam MAA for the indication general anesthesia afterwards.

Licensee activities in other territories

PAION's licensees are preparing the future filings of remimazolam in their respective territories through regulatory interactions.

Japanese licensee Mundipharma submitted a market approval dossier for remimazolam in the indication general anesthesia to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) in December 2018. Market approval could be granted end of 2019 at the earliest.

Chinese licensee Yichang Humanwell submitted a market approval dossier for remimazolam in the indication procedural sedation to the Chinese National Medical Products Administration (NMPA) in November 2018. Market approval could be granted end of 2019 at the earliest.

In November 2018, **Russian** licensee R-Pharm announced the successful completion of a Phase III trial with remimazolam in general anesthesia. R-Pharm currently plans to file for market approval in Russia by the end of 2019. For the

license territory **Turkey, Middle East and North Africa**, it is planned to file for market approval in Turkey based on the U.S. or Japanese dossier.

For **Canada**, PAION expects its licensee Pharmascience to use the U.S. market approval dossier as the basis for their own filing for market approval of remimazolam.

PAION's **South Korean** licensee Hana Pharm successfully completed patient recruitment of a Phase III trial with remimazolam in general anesthesia in October 2018. Hana Pharm plans to file for market approval by the end of 2019.

Funding activities

In June 2019, PAION and the European Investment Bank (EIB) signed a financing agreement for a loan with a total volume of up to EUR 20 million. The loan will be available until June 2021 and can be drawn down in a total of three tranches based on certain conditions as e.g. the achievement of operational milestones. PAION plans to draw down the first tranche of EUR 5 million within six months after signing. Each tranche has a term of five years and will be repaid beginning in the fourth year after drawdown.

Results of operations, financial position and net assets

Revenues in the first half-year 2019 amounted to EUR 7.5 million and resulted entirely from the milestone payment from Cosmo in connection with the submission of the NDA for remimazolam in the indication procedural sedation in the U.S. Revenues in the prior-year period primarily resulted from the license agreement with Mundipharma.

Research and development expenses amounted to EUR 6.2 million in the first half-year 2019 (prior-year period: EUR 6.5 million) and mainly relate to the ongoing EU Phase III trial in general anesthesia.

General administrative and selling expenses increased by EUR 0.6 million to EUR 2.3 million in the first half-year 2019 compared to the prior-year period. The increase mainly relates to an increase in selling expenses particularly in connection with the set-up of the supply chain for remimazolam.

Income taxes amounted to EUR 1.2 million in the first half-year 2019 (prior-year period: EUR 1.5 million) and relate to tax claims for reimbursement of parts of the research and development expenses from the British tax authorities. The decrease is primarily attributable to a cap of the claim based on the net result.

The **net income** for the first half-year 2019 amounted to EUR 0.6 million compared to a net loss of EUR 6.2 million in the prior-year period. This means an increase of the net result in the amount of EUR 6.8 million compared to the first half-year 2018, which is mainly attributable to higher revenues than in the prior-year period.

The increase in **equity** of EUR 0.6 million, compared to 31 December 2018, to EUR 21.4 million as of 30 June 2019 mainly results from the positive net result of

the first half-year 2019. As of 30 June 2019, the equity ratio was 83.3% (31 December 2018: 85.6%).

Cash and cash equivalents increased by EUR 2.0 million in the first half-year 2019 to EUR 19.2 million at the end of the current reporting period.

The increase of cash and cash equivalents particularly stems from positive **cash flows from operating activities** of EUR 2.0 million in the first half-year 2019. These primarily resulted from the net income and receipt of the milestone payments from Mundipharma and Hana Pharm recognized as trade receivables at the beginning of the fiscal year.

Risks and opportunities

Material risks and opportunities relating to future development were presented in detail in the group management report for the fiscal year 2018. Risks and opportunities have not changed significantly in the first half of 2019.

Outlook 2019

Outlook on Development and Commercialization Activities

PAION's major focus for the remainder of 2019 is on the development program in Europe, the ongoing global regulatory processes as well as the manufacture of and supply chain for remimazolam. Moreover, PAION expects the development and approval activities in all territories to also further advance the other indications.

Also, PAION is conducting small-scale pre-marketing activities for the preparation of an own commercialization for remimazolam in selected European markets.

Financial outlook 2019

PAION expects revenues of about EUR 8 million in 2019, thereof EUR 7.5 million already recognized in connection with the regulatory filing for remimazolam in the U.S. by Cosmo, which took place in April 2019. Moreover, EUR 0.5 million are related to revenues from R-Pharm in connection with the transfer of the Japanese filing dossier translated into English or transfer of the U.S. filing dossier.

Due to the ongoing investment in the development of remimazolam including the EU Phase III study, PAION expects research and development expenses to amount to between approx. EUR 13 million and approx. EUR 15 million, depending on the progress of development. Income from tax credits on parts of research and development expenses from British tax authorities is expected to amount to approx. EUR 2 million. General administrative and selling expenses are expected to amount to between approx. EUR 4 million and approx. EUR 5 million depending on the volume of precommercial activities. Net loss is expected to amount to between approx. EUR 7 million and approx. EUR 10 million in 2019.

This outlook assumes that PAION and licensee activities progress as expected. In case of delays, essential cost blocks would shift into 2020 or subsequent periods. Plans are also based on the current status of discussions with regulatory authorities.

Based on current planning, cash and cash equivalents at hand, including expected tax credits from the British tax authorities on parts of research and development expenses, secure a liquidity runway into the second half of 2020. PAION expects to require further funds of approx. EUR 10 million until filing for market approval in general anesthesia in the EU. This cash requirement could partially or completely be covered by the financing agreement with the EIB. In addition, PAION is looking into complementing financing measures as additional funds will be required in the next years for the planned own commercialization in selected European markets as well as the intended development of the indication ICU sedation and for the multi-year PIP. The magnitude of the required funds will be dependent on the actual setup of commercialization and which European countries PAION will initially focus on as well as the timing and the amount of milestone payments and royalties from licensees.

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Key Consolidated Financial Figures, IFRS

(all figures in KEUR unless otherwise noted)	Q2 2019	Q2 2018	H1 2019	H1 2018
Revenues	7,500	260	7,500	517
Research and development expenses	-3,110	-3,184	-6,173	-6,544
General administrative and selling expenses	-1,336	-966	-2,321	-1,761
Result for the period	3,827	-3,118	586	-6,243
Earnings per share in EUR for the period (basic)	0.06	-0.05	0.01	-0.10
Earnings per share in EUR for the period (diluted)	0.06	-0.05	0.01	-0.10

	H1 2019	H1 2018
Cash flow from operating activities	1,990	-6,626
Cash flow from investing activities	-4	-12
Cash flow from financing activities	-25	5,067
Change in cash and cash equivalents (incl. exchange rate differences)	1,965	-1,572
Average number of employees in the Group	44	38

	30 June 2019	31 Dec. 2018
Intangible assets	2,119	2,212
Cash and cash equivalents	19,192	17,227
Equity	21,384	20,822
Current liabilities	4,258	3,501
Balance sheet total	25,672	24,323

The full half-year financial report will be available as of 07 August 2019 on PAION's website at http://www.paion.com/media-and-investors/investorcenter/financial-reports/.

Conference call and webcast
In addition to the publication of results, the Management Board of PAION AG will host a conference call (conducted in English) on 07 August 2019 at 2 p.m. CEST (1 p.m. BST, 8 a.m. EDT) to present the financial results of the first six months of 2019 and provide a pipeline and strategy update and financial outlook.

To access the call, please dial:

- Germany +49 (0) 69 7104 45598,
- UK +44 (0) 20 3003 2666 and
- U.S. +1 212 999 6659
- Other countries: please use the UK number

When prompted, please provide the password "PAION". The conference call will be supplemented by a webcast presentation which can be accessed during the call at the following link: view-w.tv/819-1574-22109/en.

About PAION
PAION AG is a publicly listed specialty pharmaceutical company developing and aiming to commercialize innovative drugs for out-patient and hospital-based sedation, anesthesia and critical care services. PAION's lead compound is remimazolam, an intravenous, ultra-short-acting and controllable benzodiazepine sedative/anesthetic drug candidate for which PAION has completed the clinical development for use in procedural sedation in the U.S. and its local licensee Cosmo Pharmaceuticals submitted a New Drug Application in April 2019. In Japan, licensee Mundipharma filed for market approval for remimazolam in general anesthesia in December 2018. In China, licensee Yichang Humanwell filed for market approval for remimazolam in procedural sedation in November 2018.

In Europe, PAION is seeking approval for remimazolam in the indications general anesthesia and procedural sedation. For the development of remimazolam in general anesthesia, PAION is currently conducting a Phase III trial in Europe. The submission of an MAA in procedural sedation in the EU is planned based on the U.S. development program.

Development of remimazolam for intensive care unit (ICU) sedation is part of the longer-term life-cycle plan for remimazolam.

PAION's vision is to become an acknowledged "PAIONeer" in sedation and anesthesia. PAION is headquartered in Aachen (Germany) with an additional site in Cambridge (United Kingdom).

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